

(19) World Intellectual Property Organization
International Bureau



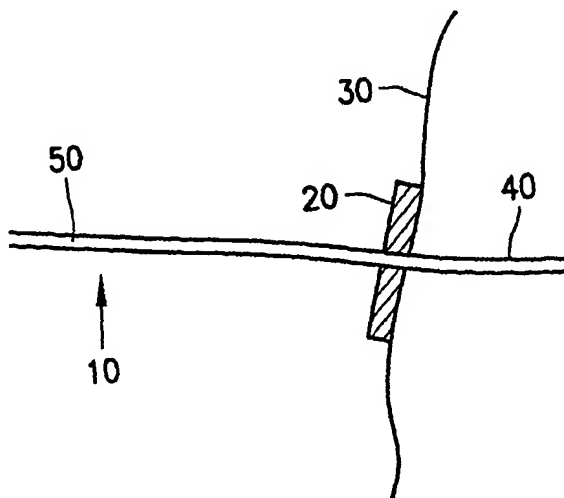
(43) International Publication Date
8 March 2001 (08.03.2001)

PCT

(10) International Publication Number
WO 01/15526 A1

- (51) International Patent Classification⁷: A01N 25/10
- (21) International Application Number: PCT/US00/21368
- (22) International Filing Date: 4 August 2000 (04.08.2000)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
09/386,187 31 August 1999 (31.08.1999) US
- (71) Applicant: STS BIOPOLYMERS, INC. [US/US]; 336 Summit Point Drive, Henrietta, NY 14467 (US).
- (72) Inventors: WHITBOURNE, Richard, J.; 2500 East Avenue, Unit 8R, Rochester, NY 14610 (US). ZHANG, Xi-anning; 36 Grouse Point, Webster, NY 14580 (US).
- (74) Agents: MELORO, Thomas, J. et al.; Kenyon & Kenyon, One Broadway, New York, NY 10004 (US).
- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.
- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
- Published:
— With international search report.
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: ANTI-INFECTIVE COVERING FOR PERCUTANEOUS AND VASCULAR ACCESS DEVICES AND COATING METHOD



(57) Abstract: A kit comprising an insertable medical device and a disc, both capable of having anti-infective properties. The disc (20) can be placed against a body surface (30) so that it surrounds and abuts the insertable portion of the device (10) which extends from the body surface. This arrangement can reduce or eliminate contamination associated with such devices, and permits such devices to remain in place for longer periods of time compared to conventional devices and methods of using those devices.

WO 01/15526 A1

ANTI-INFECTIVE COVERING FOR PERCUTANEOUS AND
VASCULAR ACCESS DEVICES AND COATING METHOD

Field of the Invention

5 The present invention relates to a kit comprising an insertable or implantable
medical device for use in combination with a disc, having anti-infective properties capable
of reducing the incidence and/or severity of infections occurring at or associated with the
site of insertion on the bodily surface of such devices.

Background of the Invention

10 Insertable or implantable medical devices include, but are not limited to needles,
infusion sets, peripheral venous catheters and needles, central venous catheters, arterial
catheters, epidural and spinal catheters, dialysis catheters, percutaneous nephrostomy and
cystostomy tubes. Before such devices are used, for example, to introduce various
materials such as nutrients or therapeutic agents into patients, or to drain material from a
15 patient, they must be inserted into the patient's body. In the course of placing a device,
contamination can occur, as individuals often proceed in an *ad hoc* fashion. Typically,
when a needle or catheter is inserted, the area of insertion is cleaned with an antiseptic.
For example, this can be done by wiping the area with a swab saturated with 70% alcohol.
Often, the site will be palpated after swabbing, occasionally contaminating the site.

20 When such devices are left in place, even for a few days, infections often result.
Exudate often seeps from the insertion site. The exudate picks up skin flora which can
diffuse back into the patient along the wetted device surface, thereby causing infection.

Many investigators have tried to solve this problem. For example, placement of a

junction seal after placement of a urinary catheter has been examined for preventing bacteriuria and reducing mortality. In one study, the incidence of bacteriuria was higher in a control group than in a treatment group for some of the potential risk factors studied, yet the differences were not statistically significant. (T.S. Huth, Arch. Intern. Med. 152:807, 1992). Lubricants containing polymyxin B or placebo were used with catheters impregnated with tetramethylthiuramdisulfide and a cyclic thiohydroxamic proprietary agent and no significant difference between these types of catheters and catheter care was seen (H.K.I. Bulter, J. Urol. 100:560, 1968). Catheters designed for instillation of intraurethral antibacterial lubricants also were not efficacious in reducing the incidence of infections. (C.M. Kunin, J. Urol. 106:928, 1971). Further, initial reports that silver coating of catheters prevented the adherence and growth of *Escherichia coli* and *Pseudomonas aeruginosa* in vitro without causing cell toxicity, led to the use of silver oxide urinary catheters. (H. Liedberg, J. Urol. 17:357, 1989; H Liedberg, Urol. Res. 17:359, 1989). However, a large clinical trial of silver oxide coated urinary catheters in selected patients yielded similar rates of infection between the silver coated group and the uncoated control silicone catheter group. (J.R. Johnson, J. Infect. Dis. 162:1145, 1990). Coated central venous catheters demonstrated a lower catheter colonization rate than observed in uncoated controls. (Veentra, JAMA 281:261, 1999; Collins, Chest 115:1632, 1999). In contrast, other studies reported no benefit to the use of coated central venous catheters. (Bach, Crit. Care Med. 27:515 1999).

Some wound healing products contain films or hydrogel layers which may be wetted with liquid materials to promote wound healing. For example, hydrogel wound dressing products are described in U.S. Patent Nos. 5,204,110, and 5,112,618. Examples

of bandages for wound dressings which contain therapeutic agents are described in U.S. Patent Nos. 5,260,066 and 5,322,695. However, such products are not suitable for limiting infection at the insertion site of an insertable or implantable medical device.

Hence, there remains a need for a method and products for limiting the degree of contamination, including preventing or reducing the growth of microorganisms within an exudate, at the insertion site of an insertable or implantable medical device.

Summary of the Invention

The present invention provides a kit useful for preventing or inhibiting the development of infections arising from insertion or implantation of a medical device through a bodily surface. The kit comprises an insertable medical device and a disc. The device has a portion that can be inserted or implanted into the body. Part of, or the entire surface of, the portion of the device that can be inserted or implanted into the body is coated with an anti-infective coating.

The disc can be used with any insertable medical device. The disc can be provided with anti-microbial properties by being coated or saturated with an antimicrobial composition. According to the invention, a preferred composition comprises at least one antimicrobial agent capable of exhibiting antimicrobial activity when essentially dry or when solvated after being essentially dry.

The disc preferably is capable of being penetrated by the device. Alternatively, the disc can be placed around the device. In use, the disc should be in contact with the body surface and surrounds and abuts the portion of the insertable portion of the device that projects from the surface of the body.

Another aspect of this invention provides a kit comprising a medical device and disc, as well as a swab, wetted with an anti-infective coating solution. The swab preferably is used to coat the insertable portion of the device, before the device is placed into the body. The kit of the invention can also include an absorbent pad wetted with an antimicrobial composition. The insertable medical device can be placed into subcutaneous tissue, a peripheral vein, a central vein, an artery, a physiologic body cavity or a pathologic cavity.

The disc can have a sufficient amount of adhesive on one surface to adhere the disc to the body surface and can be flexible, porous and/or absorbent. Examples of materials that the disc can be composed of are polypropylene, polyethylene, and woven materials composed of polyester, rayon or cotton.

In one embodiment of the invention, the disc comprises at least two layers. A first layer can be placed against the body surface, and preferably is permeable to the antimicrobial agent. A second layer preferably contains an antimicrobial agent in a solvated or dry form, such that the antimicrobial agent can permeate through the first layer.

The invention includes a method of inhibiting or reducing the incidence of infection associated with inserting a medical device in a patient, wherein an insertable surface of said device is coated, at least in part, with an anti-infective coating, which comprises inserting the device in a patient such that a portion of an inserted surface of the device projects from a bodily surface. A disc is contacted with the bodily surface where the device projects from the bodily surface such that said disc surrounds and abuts the inserted surface projecting from the bodily surface, wherein the disc is coated or saturated with an antimicrobial composition. The composition comprises at least one antimicrobial

agent capable of exhibiting antimicrobial activity when in a substantially dry state or when solvated after being in a substantially dry state.

Brief Description of the Drawings

5 Figure 1 is a side view of a kit of the invention.

Figure 2 is a side view of a second embodiment of a kit of the invention.

Detailed Description of the Preferred Embodiments

Referring to Figure 1, the invention is directed to a kit comprising an insertable
10 medical device 10 and a disc 20. The insertable medical device 10 is capable of
penetrating or passing through a body surface 30. The device comprises a distal portion 40
that is capable of being inserted or implanted into the body and a proximal portion 50 that
remains outside the body. Sites within the body that can be accessed by the device include
but are not limited to vascular and subcutaneous sites, body cavities, potential spaces, and
15 pathologic cavities. The device includes but is not limited to infusion devices, such as
peripheral venous catheters and indwelling infusion needles, such as butterfly needles,
subcutaneous access devices such as those used with insulin pumps and patient controlled
analgesia (PCA) pumps, arterial catheters, central venous catheters, dialysis catheters,
including peritoneal dialysis catheters, nephrostomy catheters, percutaneous cystostomy
20 catheters, indwelling paracentesis and pleurocentesis catheters and drains, and spinal and
epidural catheters.

The outer surface of the distal portion 50 of the insertable medical device
preferably is coated with an anti-infective coating, partially or over its entire surface.

Optionally, the proximal portion 40 of the device also can be coated with the anti-infective coating.

The anti-infective coating is capable of reducing or eliminating any contamination that occurs during the introduction of the device into the body and has antiseptic, antibiotic, disinfectant, antiviral, and/or antifungal properties. The anti-infective coatings include, but are not limited to, those described below and the anti-infective coatings described in U. S. Patent Nos. 5,069,899 and 5,525,348, each of which are incorporated in their entirety herein by reference. In one embodiment of the invention, a swab wetted with the anti-infective coating optionally is provided so that the device can be coated by wiping the device with the swab and allowing it to dry before insertion.

The disc 20 is substantially planar and is composed of an absorbent or non-absorbent material, preferably, an absorbent material. Examples of appropriate materials include, but are not limited to, plastic foams, cotton gauzes, or porous filter material, polypropylene film, polyethylene film, and woven materials composed of polyester, rayon or cotton. As used herein, the term disc includes an object having a surface capable of contacting a bodily surface, regardless of the actual shape. In practice the disc 20 can be circular, rectangular, or any other suitable shape. Hence, the disc 20 is of a shape and size appropriate to the type of medical device and the location where the device 10 is placed. For example, a larger bore access device may require a larger disc 20 than a smaller bore device. A circular disc 20 with a diameter of approximately 2.5 cm can be used for a small needle device. A peritoneal dialysis catheter may require a substantially larger disc 20 measuring up to 15 cm in size and preferably rectangular in shape.

As shown in Figure 2, another embodiment of the present invention comprises an

absorbent pad 60 used in combination with a coated disc 20 to form the disc. The coated disc 20 preferably is composed of a flexible inert material. Suitable materials include but are not limited to polypropylene film and polyethylene film, woven materials composed of polyester, rayon and cotton. The coated disc 20 can be rendered permeable by the presence of a multitude of fine perforations. The fine holes permit easier penetration of the disc 20 by the insertable portion of the device 10. The holes allow access of the solution contained within the disc 20 to the body surface 30, and also allow drainage of any exudate or transudate from the body surface entry site, which can solvate the dried anti-infective composition permitting it to exert its anti-infective properties at the site where the insertable medical device 10 enters the body. The absorbent pad 60 is composed of a material capable of absorbing or being soaked or wetted by the antimicrobial composition. Examples of appropriate materials include, but are not limited to, plastic foams, cotton gauzes, or porous filter material.

The disc 20 has an anti-infective coating. The coating is applied to one or both sides of the disc 20 and allowed to dry, so that the disc 20 preferably is dry when applied to the skin. In the preferred embodiment of the present invention, the disc 20 is of approximately the same size and shape as the absorbent pad 60. However, the absorbent pad 60 and coated disc 20 also can have different sizes and shapes. Optionally, the disc and pad may be adhered to one another. In addition, the disc 20 may be provided with an adhesive material at one surface which permits the disc to adhere to the body surface 30. In use, the disc 20 preferably contacts the body surface 30. The absorbent pad 60 preferably contacts the disc 20, separated from the body surface 30 by the coated disc 20. If only one side of the disc is coated with antimicrobial composition, the coated side preferably is

placed against the body surface 30. The system is secured to the skin with an adhesive material such as adhesive tape.

The disc 20 can be coated, impregnated or saturated or otherwise provided with an antimicrobial composition with antiseptic, antibiotic, disinfectant, antiviral, and/or antifungal properties. An amount of antimicrobial solution is provided to the disc, which is sufficient to provide an effective amount of the antimicrobial agent, and which preferably is sufficient to render the disc substantially wet when used.

Suitable antimicrobial compositions useful in the invention include solutions of bacteriocides, antibiotics, antifungal agents, antiviral agents, and/or antiseptics that are suitable for human use. Suitable agents include, but are not limited to 2-bromo-2-nitropropane-1,3-diol (sold under the trade name Bronopol[®]), polyhexanide (sold under the trade name Cosmocil CQ[®]), and benzalkonium chloride. Suitable solvents include those that are compatible with the bacteriocides, antibiotics, antifungal agents, antiviral agents, and/or antiseptics, and appropriate for human use. Preferred solvents include, but are not limited to one, or preferably more than one of the following, ethanol, saline solution, more preferably Normal saline solution, tetrahydrofuran, and benzyl alcohol. Preferably, glycerine or polyethylene glycol (PEG), more preferably PEG 400 is a component of the composition. Other suitable solvents can be used.

In one embodiment of the invention, corticosteroids are included in the antimicrobial composition. Suitable corticosteroids, include synthetic and natural corticosteroids. In a preferred embodiment dexamethasone is used. Other suitable corticosteroids include, but are not limited to, alclometasone dipropionate, amcinonide, betamethasone, clobetasol propionate, clocortolone pivalate, cortisone, hydrocortisone,

desonide, desoximetasone, diflorasone diacetate, fluocinolone acetonide, fluocinonide, fluandrenolide, halcinonide, methylprednisolone, mometasone furoate, and triamcinolone.

The antimicrobial composition used with the disc 20 preferably contains a polyurethane resin, more preferably 2% to 10% by weight polyurethane resin, most preferably 4% to 6% by weight polyurethane resin. A preferred solvent, ethanol, preferably contains 1% to 10% by weight nitrocellulose, and more preferably also contains 2% to 4% polyurethane resin. Preferred antimicrobial agents include, but are not limited to, benzalkonium chloride and/or 2-bromo-2-nitropropane-1,3-diol. A preferred embodiment of the present invention employs an antimicrobial composition comprising nitrocellulose in ethanol, tetrahydrofuran, and benzyl alcohol in a ratio of 2:15:1 by weight, with polyurethane resin, more preferably about 5% polyurethane resin, and preferably 0.2% to 1.0% of one or more of the antimicrobial agents, most preferably 0.5% of the antimicrobial agent or agents. The disc can be coated with the composition and then can be dried by heating, such as by heating in an oven at about 40°C to 60°C, most preferably at about 50°C.

The disc 20 preferably surrounds and abuts the insertable portion of the device 10 at a position on device 10 where a portion of the device 10 projects from the body surface 30. In one embodiment of the invention, the disc 20 is placed onto the body surface 30 and the insertable portion of the device is then passed through the disc 20 into the body. In another embodiment, the insertable portion of the device is passed through the center of the disc 20, and is then inserted into the body. In a third embodiment, the kit is packaged with the disc 20 already in place on the device 10. In another embodiment of the present invention the disc 20 has an opening or slit extending from a radially interior portion to its

edge. In this embodiment, the disc 20 is placed on the body surface 30, around the device 10 after the device 10 has been inserted into the body.

The disc 20 preferably is wet when applied to body surface 30 and when the device 10 is inserted into the body. The disc 20 then is permitted to dry, leaving the anti-infective material in or on the disc 20. If an exudate develops at the access site, it can be absorbed by the disc 20. The exudate can solubilize or solvate the anti-infective material, which can exert an anti-infective effect at the site, limiting or preventing infection. In one embodiment of the invention, only the disc 20 is supplied for use with the medical access device 10 of the user's choice. Optionally, a swab wetted with the anti-infective coating can be supplied for coating the selected medical access device.

The examples listed below are illustrative and are not intended to limit the scope of the invention.

EXAMPLE 1.

15 Anti-Infective Solutions

The solutions used in the Examples 2 to 5 are as follows:

Solution A

PEG 400	3 gm
Ethanol	12 gm
20 2-bromo-2-nitropropane-1,3-diol	0.05 gm
Polyhexanide	0.25 gm
Dexamethasone	0.03 gm

Solution B

PEG 400	4.4 gm
Ethanol	19.2 gm
0.9% saline	18 gm
5 Sodium chloride	0.27 gm
2-bromo-2-nitropropane-1,3-diol	0.15 gm
Polyhexanide	0.75 gm
Dexamethasone	0.12 gm

10

5BRON

0.5% 2-bromo-2-nitropropane-1,3-diol and 5% polyurethane resin in:

3% nitrocellulose in a solvent of ethanol, tetrahydrofuran, and benzyl alcohol

2/15/1 by weight

15

5BAK

0.5% benzalkonium chloride and 5% polyurethane resin in:

3% nitrocellulose in a solvent of ethanol, tetrahydrofuran, and benzyl alcohol, in a

ratio of 2:15:1, by weight

1BRON

PEG 400	12 gm
Ethanol	48 gm
2-bromo-2-nitropropane-1,3-diol	0.4 gm

5

BRONBAK

0.5% 2-bromo-2-nitropropane-1,3-diol, 0.5% Benzalkonium chloride, and 5% polyurethane resin, in 3% nitrocellulose in ethanol, tetrahydrofuran and benzyl alcohol 2/15/1 by weight

10

EXAMPLE 2Method for Making Discs

An anti-infective disc was made by manually coating a 0.0005" thick polypropylene sheet with about 3 ml of 5BRON. The sheet then was dried in an oven at 50°C for 60 minutes for each coated side. Discs of 2.5 cm diameter were cut from the coated sheet. Other discs coated with 5BAK and with BRONBAK were made from sheets of 0.0005" thick polypropylene in a similar manner, except that 5BAK and BRONBAK were substituted for 5BRON.

15

20

EXAMPLE 3Method of Using 5BRON Coated Disc

A Clinipad® alcohol wipe was dried out and saturated with Solution A. A butterfly needle (PolyfinQQ® Ref-365 bent needle) was coated with Solution A using a cotton

tipped swab and air dried for a few minutes. A disc coated with 5BRON was placed over an insertion site of a human subject. An alcohol wipe saturated with Solution B was placed over the disc. Thereafter, the coated, bent needle was inserted through the alcohol wipe and disc into subcutaneous tissue. The needle was secured using dressing tape. The needle
5 was removed aseptically using sterile gloves 7 days after insertion. On gross physical examination, the needle site did not appear to be infected. After removal, the needle tip was cut using sterile cutters and dropped into a tube containing Phosphate Buffer with Tween 80. The buffer was vortexed for 30-45 seconds. A sterile swab was used to streak three Standard Method Agar (SMA) plates, which were then streaked for isolation. The
10 plates were incubated for 5 to 7 days at $37 \pm 2^\circ\text{C}$. Resulting colonies were identified, and moderate growth of gram positive cocci and gram negative coccobacilli was reported from the cultured needle tip.

EXAMPLE 4

15 Method for Using 1BRON and 5BAK Solutions

A MiniMed® MMT-365 infusion set was placed as described below. An alcohol wipe was allowed to dry, and saturated with 1BRON by placing the wipe in a vessel containing 1 BRON. An insertion site for a human subject was wiped with a second alcohol wipe. A polypropylene disc coated was coated with 5BAK, allowed to dry, and was placed on the
20 insertion site. Thereafter, the alcohol wipe saturated with the 1BRON solution was placed over the disc on the insertion site. Next, the bent needle was swabbed with 1BRON solution, inserted through the alcohol wipe saturated with 1BRON solution, through the disc, into the skin, and secured in place using surgical adhesive tape. After 5 days in place,

the needle was removed. The site was clean and did not appear to be infected.

EXAMPLE 5

Use of BRONBAK Solution and Culture Results

5 A. BRONBAK Studies

BRONBAK coated discs were used in tests that were conducted as described in Example 3. A dried alcohol swab saturated with Solution B and a needle coated with Solution A were used. The needle tip was cultured for bacteria after removal, as described in Example 3. The results of the cultures are shown in Table 1.

10

TABLE 1

Bacterial Culture Results of Needle Tips after Use of Invention

15

Test Number	Days inserted	Disc Coating	Culture Results
1	7	5BRON	No Growth
2	7	BRONBAK	No Growth
3	6	BRONBAK	Light Growth
4	5	BRONBAK	No Growth
5	9	BRONBAK	No Growth

20

B. Control Experiments

25

Additional control experiments were conducted in which the anti-infective technology of the instant invention was not used. Instead, needle insertion was conducted following the practice generally described above. The results are shown in Table 2.

Table 2

Bacterial Culture Results of Needle Tips Without Use of Invention

Test Number	Days inserted	Disc Coating	Gauze Coating	Needle Coating	Needle Tip Culture
6	2	No Disc	No Gauze	None	No Growth
7	2	No Disc	No Gauze	None	No Growth
8	3	No Disc	No Gauze	None	No Growth
9	3	No Disc	No Gauze	None	No Growth

An additional control experiment was conducted in which needle insertion was conducted following practice generally as described above. A site on the left side of the anterior abdomen was wiped with an alcohol soaked pad (Clinipad® alcohol wipe). Then a butterfly needle (Minimed Polyfin QQ® with wings infusion Set Ref, MMF-365) was placed through the skin into the subcutaneous tissue, and the site was covered with sterile dressing tape. After four days the site had become infected, and the needle had to be removed.

We claim:

1. A kit comprising:

an insertable medical device having an insertable surface; and

a disc provided with an antimicrobial composition, said composition comprising at least one antimicrobial agent capable of exhibiting antimicrobial activity when in a substantially dry state or when solvated after being in a substantially dry state, said disc being capable of surrounding and abutting said insertable surface when a portion of said insertable surface projects from a bodily surface, and said disc is in contact with said bodily surface.
2. The kit of claim 1, further comprising a swab with an anti-infective solution for providing said implantable surface with an anti-infective coating before said device is inserted.
3. The kit of claim 1, further comprising an absorbent pad saturated with an antimicrobial composition comprising at least one antimicrobial agent capable of exhibiting antimicrobial activity when in a substantially dry state or when solvated after being in a substantially dry state, said pad being capable of surrounding and abutting said insertable surface while said pad is in contact with said disc .
4. The kit of claim 1, wherein said device is constructed and arranged for insertion into a vehicle selected from the group consisting of subcutaneous tissue, a peripheral vein, a central vein, an artery, a physiologic body space or a pathologic space.

5. The kit of claim 1, wherein said disc is provide with a sufficient amount of an adhesive to adhere said disc to said bodily surface.
6. The kit of claim 1, wherein said anti-infective coating comprises a solvent; a antimicrobial agent, and a corticosteroid.
7. The kit of claim 6, wherein said anti-infective coating comprises a polyethylene glycol; 2-bromo-2-nitropropane-1,3-diol; polyhexanide; and dexamethasone.
8. The kit of claim 1, wherein said antimicrobial composition comprises a polyurethane resin, nitrocellulose in ethanol, tetrahydrofuran, benzyl alcohol, and an antimicrobial agent.
9. The kit of claim 8, wherein said antimicrobial agent is selected from the group consisting of an antiseptic, antibiotic, disinfectant, antiviral agent and antifungal agent, and mixtures thereof.
10. The kit of claim 1, wherein said antimicrobial composition contains one or more agents selected from the group consisting of 2-bromo-2-nitropropane-1,3-diol, benzalkonium chloride, polyhexanide, bacitracin, neomycin, silver sulfadiazine, AgCl, and chlorhexidine.
11. The kit of claim 10, wherein said antimicrobial agent is selected from the group consisting of 2-bromo-2-nitropropane-1,3-diol and benzalkonium chloride.

12. The kit of claim 1, wherein said antimicrobial composition comprises PEG 400 in an amount from about 15% to about 25% w/w; ethanol in an amount from about 70% to about 85% w/w; dexamethasone in an amount from about 1% to about 3% w/w; 2-bromo-2-nitropropane-1,3-diol in an amount from about 0.30% to about 0.40% w/w; and polyhexanide in an amount from about 1.5% to about 2.0%.

13. The kit of claim 1, wherein said antimicrobial composition comprises polyethylene glycol; ethanol; a corticosteroid; 2-bromo-2-nitropropane-1,3-diol; polyhexanide; and a saline solution.

14. The kit of claim 13, wherein said antimicrobial composition comprises PEG 400 in an amount from about 8% to about 12% w/w; ethanol in an amount from about 40% to about 50% w/w; Normal saline in an amount from about 35% to about 45%; dexamethasone in an amount from about 0.2% to about 0.3% w/w; 2-bromo-2-nitropropane-1,3-diol in an amount from about 0.30% to about 0.40% w/w; and polyhexanide in an amount from about 1.5% to about 2.0%.

15. The kit of claim 1, wherein said antimicrobial composition comprises a polyurethane resin; nitrocellulose in ethanol; tetrahydrofuran; benzyl alcohol; and a substance chosen from the group consisting of 2-bromo-2-nitropropane-1,3-diol and polyhexanide.

16. The kit of claim 15, wherein said antimicrobial composition comprises: 2-bromo-

2-nitropropane-1,3-diol in an amount from about 0.1% to about 2.0% w/w; polyurethane resin in an amount from about 3% to about 7% w/w; from about 2% to about 4% by volume nitrocellulose in ethanol, in an amount from about 7% to about 12% w/w; tetrahydrofuran in an amount from about 80% to about 90% w/w; and benzyl alcohol in an amount from about 4% to about 6% w/w.

17. The kit of claim 1, wherein said antimicrobial composition comprises: benzalkonium chloride in an amount from about 0.1% to about 2.0% w/w; polyurethane resin in an amount from about 3% to about 7% w/w; from about 2% to about 4% by volume nitrocellulose in ethanol, in an amount from about 7% to about 12% w/w; tetrahydrofuran in an amount from about 80% to about 90% w/w; and benzyl alcohol in an amount from about 4% to about 6% w/w.

18. The kit of claim 1, wherein said disc is permeable.

19. The kit of claim 1, wherein said disc is made of an absorbent material.

20. The kit of claim 1, wherein said disc is composed of a material selected from the group consisting of polypropylene, polyethylene, and woven materials selected from the group consisting of polyester, rayon and cotton.

21. The kit of claim 1, wherein said disc comprises a permeable layer adapted to be placed adjacent to a bodily surface, and a second layer containing an antimicrobial agent

capable of permeating into and through said first layer.

22. A method of inhibiting the incidence of infection associated with insertion of a medical device in a patient, which method comprises:

inserting said device in a patient such that a portion of said device projects from a bodily surface; and

contacting a disc with said device where said device projects from said bodily surface such that said disc surrounds and abuts said insertable device projecting from said bodily surface, wherein said disc is provided with an antimicrobial composition, said composition comprising at least one antimicrobial agent capable of exhibiting antimicrobial activity when in a substantially dry state or when solvated after being in a substantially dry state.

23. The method of claim 22, wherein said device penetrates said disc prior to being inserted into said patient.

24. The method of claim 22, wherein said device is provided with an anti-infective coating containing one or more agents selected from the group consisting of 2-bromo-2-nitropropane-1,3-diol, benzalkonium chloride, polyhexanide, bacitracin, neomycin, silver sulfadiazine, AgCl, and chlorhexidine.

25. The method of claim 24, wherein said antimicrobial composition provided with said disc contains one or more agents selected from the group consisting of 2-bromo-2-

nitropropane-1,3-diol, benzalkonium chloride, polyhexanide, bacitracin, neomycin, silver sulfadiazine, AgCl, and chlorhexidine.

26. The method of claim 25, wherein said antimicrobial composition comprises: 2-bromo-2-nitropropane-1,3-diol in an amount from about 0.1% to about 2.0% w/w; polyurethane resin in an amount from about 3% to about 7% w/w; from about 2% to about 4% by volume nitrocellulose in ethanol, in an amount from about 7% to about 12% w/w; tetrahydrofuran in an amount from about 80% to about 90% w/w; and, benzyl alcohol in an amount from about 4% to about 6% w/w.

27. The method of claim 24, wherein said antimicrobial composition comprises: benzalkonium chloride in an amount from about 0.1% to about 2.0% w/w; polyurethane resin in an amount from about 3% to about 7% w/w; in a concentration from about 2% to about 4% nitrocellulose in ethanol in an amount from about 7% to about 12% w/w; tetrahydrofuran in an amount from about 80% to about 90% w/w; and benzyl alcohol in an amount from about 4% to about 6% w/w.

28. A device comprising:

a disc provided with an antimicrobial composition, said composition comprising at least one antimicrobial agent capable of exhibiting antimicrobial activity when in a substantially dry state or when solvated after being in a substantially dry state; and, said disc being capable of surrounding and abutting an inserted surface of an insertable medical device, when a portion of said inserted surface projects from a bodily

surface, and said disc is in contact with said bodily surface.

29. A kit comprising:

an insertable medical device, with an insertable surface, wherein said surface is provided with an anti-infective coating; and

a disc provided with an antimicrobial composition, said composition comprising at least one antimicrobial agent capable of exhibiting antimicrobial activity when in a substantially dry state or when solvated after being in a substantially dry state, said disc being capable of surrounding and abutting said insertable surface when a portion of said insertable surface projects from a bodily surface, and said disc is in contact with said bodily surface.

1/1

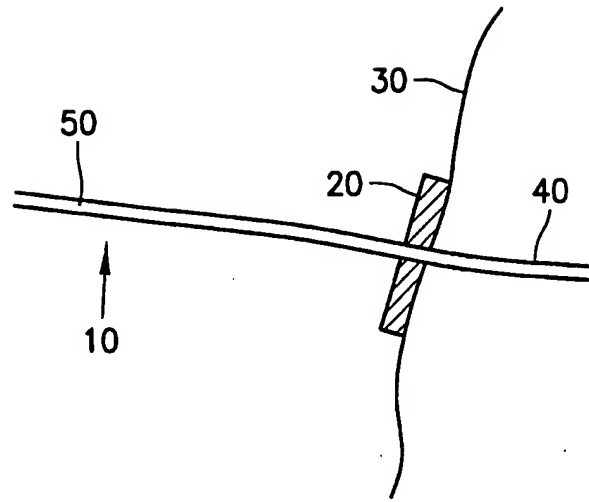


Fig. 1

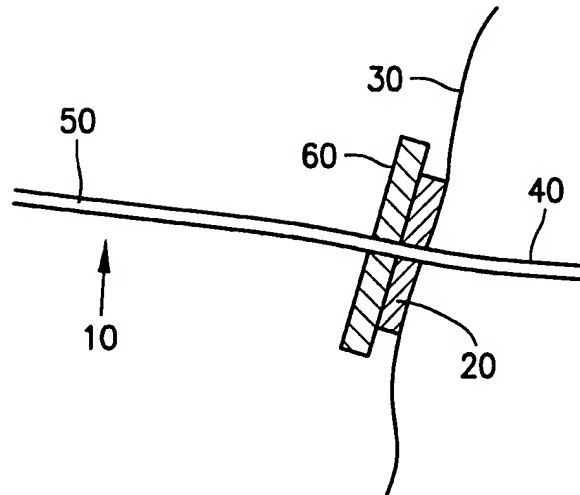


Fig. 2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/21368

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A01N 25/10

US CL : 424/409

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/405, 408, 409, 417

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	DE 3 830 359 A1 (WEIKL) 14 December 1989, see Figures 1 and 5 and columns 1-6.	1, 4, 18-23, 28, 29 ----- 1-29
X --- Y	US 4,054,139 A (CROSSLEY) 18 October 1977, see Figures 1-3 and columns 1-4.	1, 4, 18-23, 28, 29 ----- 1-29
Y	US 5,260,066 A (WOOD et al.) 09 November 1993, see entire document.	1-29

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*g* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

07 SEPTEMBER 2000

Date of mailing of the international search report

22 SEP 2000

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

NEIL LEVY

Telephone No. (703) 308-1235